

REMARKS

I. Status of Claims

Independent claim 1 is amended to incorporate the limitations of claims 3 and 9, and it is presently directed to “a method of producing a coated preparation, which comprises coating a core containing an active ingredient.” Dependent claims 4-8 are amended accordingly to reflect the amendments to claim 1. Independent claim 10 is also amended to incorporate the limitations of claim 9. No new matter has been introduced.

Claims 3, 9, and the non-elected claims 2, 11, and 12 are cancelled. The Applicants reserve the right to pursue the subject matter of the canceled claims in subsequent divisional applications. Therefore, claims 1, 4-8, and 10 are currently pending to be examined on their merits.

II. Specification

A new Abstract provided herein has corrected the minor informalities brought forth by the Office. Additionally, the Applicants respectfully submit that the title of the application should be replaced with “METHODS OF PRODUCING A COATED PREPARATION.”

III. 35 U.S.C. § 112, 2nd Paragraph, Rejections

Claim 1 has been amended to recite a method of **producing** a coated preparation, and that the method comprises coating **a core** containing an active ingredient with a dispersion of pioglitazone hydrochloride. The Applicants respectfully submit that the indefiniteness rejections should be overcome in view of the amendments and respectfully request the rejections be withdrawn.

IV. 35 U.S.C. § 102 Rejections

Claims 1, 3-7, and 10 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cutie (WO 91/82875). Without acquiescing to the grounds of rejections, independent claim 1 has been amended to incorporate the limitations of claims 3 and 9, and independent claim 10 has been amended to incorporate the limitations of claim 9. Claim 9, which recites that the organic solvent contains polyvinylpyrrolidone, has not been found to be anticipated by Cutie. Thus, with the amendments, Cutie does not teach every element recited by the claimed methods in the instant application. The Applicants thus respectfully request the anticipation rejections be withdrawn.

V. 35 U.S.C. § 103 Rejections

Original claims 1, and 3-10 are rejected under 35 U.S.C. § 103(a) as being obvious over Timmins (US 6,031,004), in view of Cutie. The Office alleges that because Timmins teaches that the thiazolidinedione oral anti-diabetic agent pioglitazone is employed and Cutie teaches a method for producing a combined formulation of pioglitazone and metformin, one of ordinary skill in the art would have been motivated to combine Timmins with Cutie to reach the claimed methods. The Applicants respectfully disagree.

(i) Current Obviousness Standard

The Supreme Court recently reaffirmed the Graham factors for determining obviousness in *KSR Int'l Co. v. Teleflex Inc.* (No. 04-1350) (U.S., April 30, 2007). The Graham factors, as outlined by the Supreme Court in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966), are: 1) determining the scope and contents of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; 3) resolving the level of ordinary skill in the pertinent art; and 4) evaluating evidence of secondary consideration. The Supreme Court recognized that a showing of "teaching, suggestion, or motivation" to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the

claimed subject matter is obvious under 35 U.S.C. § 103(a), and held that the proper inquiry for determining obviousness is whether the improvement is more than the predictable use of prior art elements according to their established functions. The Court noted that it is "important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements" in the manner claimed, and specifically stated:

Often, it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was *an apparent reason to combine the known elements in the fashion claimed* by the patent at issue. To facilitate review, this analysis should be made explicit.

KSR Int'l Co. v. Teleflex Inc., slip op. at 14 (emphasis added). As discussed below, the cited art cannot render the claimed invention obvious.

(ii) Timmins and Cutie

Timmins discloses concurrent use of pioglitazone with a metformin salt. However, it does not disclose or suggest that dispersed pioglitazone is applied in a coating on the surface of a metformin salt core, nor does it disclose polyvinylpyrrolidone used as a base in an organic solvent in the coating. In fact, polyvinylpyrrolidone is only used to produce the tablet of Timmins (see Timmins, col. 5, lines 13-19).

Cutie teaches a core with a first layer comprising pioglitazone hydrochloride (Cutie, page 2, lines 20-30). Nowhere does it teach that the pioglitazone is in a dispersed form in an organic solvent containing polyvinylpyrrolidone. Furthermore, Cutie does not teach at all the dissolution property of pioglitazone hydrochloride, which is one main advantage in utility of the products as a result of the claimed methods.

The claimed methods recite "coating a core containing an active ingredient with a dispersion of pioglitazone hydrochloride in an organic solvent, which contains polyvinylpyrrolidone." One characteristic of such coating provides a superior dissolution

property of pioglitazone hydrochloride (see Specification, page 2, lines 15-24; see also Example 1). Neither Timmins nor Cutie suggests such a property. Thus, one of ordinary skill in the art would not have been motivated to combined Timmins and Cutie to reach the instant claimed methods. In fact, even if one attempts to combine Timmins and Cutie, without the pioglitazone in a dispersion form in an organic solvent containing polyvinylpyrrolidone, one would not have expected the superior dissolution property resulting from the claimed invention. Thus, the instant claims are not obvious over Timmins or Cutie, or a combination thereof. See *KSR Int'l Co.* The Applicants respectfully request the obviousness rejections be withdrawn.

CONCLUSION

The Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, the Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Aug. 12, 2008

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